K061397

AUG 16 2006

Ace Surgical Supply Co., Inc.

Special 510(k) Notification:
ACE Surgical Orthodontic Bone Screw System

Attachment 1 – 510(k) Summary

Submitter Name:	ACE Surgical Supply Co., Inc.
Submitter Address :	1034 Pearl St., Brockton, MA 02301
Contact Person:	J. Edward Carchidi, DDS
Phone Number:	(508) 588-3100
Fax Number:	(508) 523-3140
Date Prepared:	May 2006
Device Trade Name:	ACE Surgical Orthodontic Bone Screw System
Device Common Name:	Endosseous Implant Screw
Classification Name:	Implant, Endosseous, Root form, product code DZE
Predicate device:	ACE Surgical Miniboneplate system, K951392
Reason for submission:	Not previously marketed in the USA

Device Description and Materials:
The ACE Surgical Orthodontic Screw System is a is a set of machined surgical grade titanium alloy (Ti-6Al-4V ELI) screws, intended for orthodontic use, constructed with a hole in the screw head through which a wire can be passed to fix the mandible and maxilla in orthodontic treatment. This head design also permits the use of the screw with the orthodontic appliances (bracket, wire, elastic head, etc.) The tip of the screw is designed available to self drilling and self-tapping, supplied in 1.2/1.5mm and 1.5/1.8mm tapered thread, both with a 3.0mm diameter head and in lengths of 6,8,10mm. The screw raw material is Ti-6-AL-4V ELI per ASTM F136 standard. The candidate devices are identical in materials and characteristics to that cleared under K951392. These screws are supplied sterile in standard Tyvek™ mylar packaging.

The ACE Surgical Orthodontic Bone Screw System is a comprehensive system retaining prosthetic components, auxiliary components, and surgical tools as does the predicate ACE Surgical Miniboneplate system.

Intended Use:
The ACE Surgical Orthodontic Bone Screw System is intended to be used to provide a fixed anchorage point for attachment of orthodontic appliances to facilitate the orthodontic movement of teeth. It is used temporarily and is removed after orthodontic treatment has been completed.

Substantial Equivalence/ Device Technological Characteristics and Comparison to Predicate Device(s):
The ACE Surgical Orthodontic Bone Screw System is substantially equivalent to the:
ACE Surgical Screw Miniboneplate System, K951392
KLS-Martin Ortho Anchorage System, K033483
Osteomed Orthodontic Screw System, K031936

Among the information and data presented in the 510(k) submission to support the substantial equivalency of the ACE Surgical Orthodontic Bone Screw System to the specified predicate devices are: 1) device description, 2) indications for use, 3) bench test results, 4) materials, and 5) labeling. In particular, the bench testing demonstrated there was no difference in the performance, safety, or effectiveness between the ACE Surgical Orthodontic Screw System and the specified predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 13 2007

Dr. J Edward Carchidi
President
Ace Surgical Supply Company, Limited
1034 Pearl Street
Brockton, Massachusetts 02301

Re: K061397
Trade/Device Name: ACE Surgical Orthodontic Bone Screw System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous dental implant
Regulatory Class: II
Product Code: OAT
Dated: May 15, 2006
Received: May 24, 2006

Dear Dr. Carchidi:

This letter corrects our substantially equivalent letter of August 16, 2006.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

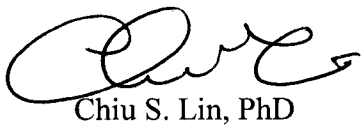
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,



Chiu S. Lin, PhD
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 3 – Indications for Use Enclosure

510(k) Number: _____

Device Name: ACE Surgical Orthodontic Bone Screw System

Intended Use / Indications for Use:

The ACE Surgical Orthodontic Bone Screw System is intended to provide a fixed anchorage point for attachment of orthodontic appliances to facilitate the orthodontic movement of teeth. It is used temporarily and is removed after orthodontic treatment has been completed. It is intended for single use only.

(PLEASE DO NOT WRITE BELOW THIS LINE/CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

[signature]

[illegible] Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

(510(k) Number K061397

Prescription Use X
(per 21 CFR 801.109)

OR

Over the Counter Use ___
Optional Format 1-2-96